

AMENDMENTS TO THE CLAIMS

Presented below is a complete set of claims with current status indicators.

1. (currently amended) A catheter for use during treatment of biological tissue within a biological organ having fluid flowing therethrough, said catheter comprising:

a shaft having a distal segment adapted to be positioned in the biological organ, the distal segment having a tissue-contacting area ~~intended to contact the biological tissue and a fluid-contacting area intended to contact the fluid~~ and a fluid-contacting area spaced apart from the tissue-contacting area, wherein the space between the two areas allows for the tissue-contacting area to contact the biological tissue while the fluid-contacting area contacts the fluid flowing through the organ;

at least one pressure sensor associated with the distal segment and positioned within the tissue-contacting area, the pressure sensor adapted to provide pressure data indicative of the pressure exerted on the distal segment at or near the pressure sensor; and

at least one flow sensor positioned within the fluid-contacting area and adapted to provide flow-rate data indicative of the flow rate of the fluid through the biological organ.

2. (original) The catheter of claim 1 further comprising an electrode system at the distal segment, the electrode system adapted to transmit energy to the biological tissue;

3. (original) The catheter of claim 2 wherein the electrode system comprises at least one electrode and the at least one pressure sensor is located on the electrode.

4. (original) The catheter of claim 2 wherein the electrode system comprises at least one electrode and the at least one pressure sensor is located on the shaft adjacent the electrode.

5. (original) The catheter of claim 2 wherein the electrode system comprises a plurality of band electrodes, a plurality of which have a pressure sensor associated therewith.

6. (original) The catheter of claim 5 wherein the pressure sensors are located on the band electrodes.

7. (original) The catheter of claim 5 wherein the pressure sensors are located on the shaft between adjacent band electrodes.

8. (original) The catheter of claim 2 wherein the electrode system comprises a plurality of band electrodes arranged in a linear array and the at least one pressure sensor is located on the shaft near the longitudinal center of the array.

9. (previously canceled)

10. (previously canceled)

11. (canceled)

12. (canceled)

13. (currently amended) The catheter of ~~claim 1~~ claim 2 wherein the electrode system comprises a plurality of band electrodes, a plurality of which have a flow sensor associated therewith.

14. (original) The catheter of claim 13 wherein the flow sensors are located on the band electrodes.

15. (original) The catheter of claim 13 wherein the flow sensors are located on the shaft between adjacent band electrodes.

16. (currently amended) The catheter of ~~claim 1~~ claim 2 wherein the electrode system comprises a plurality of band electrodes arranged in a linear array and the at least one flow sensor is located on the shaft near the longitudinal center of the array.

17. (previously presented) The catheter of claim 1 further comprising at least one temperature sensor associated with the distal segment and positioned within the tissue-contacting area, the temperature sensor adapted to provide temperature data indicative of the temperature at the interface between the temperature sensor and the tissue.

18. (currently amended) The catheter of claim 17 further comprising an electrode system at the distal segment, wherein the electrode system comprises at least one electrode and the at least one temperature sensor is located on the electrode.

19. (currently amended) The catheter of claim 17 further comprising an electrode system at the distal segment, wherein the electrode system comprises a plurality of band electrodes, a plurality of which have at least one temperature sensor located thereon.

20. (previously presented) A system for applying energy to biological tissue within a biological organ having fluid flowing therethrough, said system comprising:

a generator for providing energy;

a catheter carrying an electrode system at its distal segment, the distal segment having a tissue-contacting area adapted to be positioned in the biological organ and intended to contact the biological tissue, and the electrode system adapted to receive energy from the generator;

at least one pressure sensor associated with the distal segment, located within the tissue-contacting area and adapted to provide pressure data indicative of the pressure exerted on the distal segment at or near the pressure sensor; and

a processor responsive to the pressure data and configured to analyze the pressure data and provide an indication of contact between the distal segment at or near the pressure sensor and the tissue, wherein the indication comprises a visual display of a degree of electrode/tissue contact.

21. (original) The system of claim 20 wherein the processor is adapted to:

convert the pressure data to a measured pressure value;

compare the measured pressure value to a reference pressure value indicative of adequate contact between the distal segment at or near the pressure sensor and the tissue; and

provide an indication of adequate contact when the measured pressure value is at least as great as the reference pressure value.

22. (original) The system of claim 20 wherein the processor is adapted to:

convert the pressure data to a measured pressure value;

determine the percentage difference between a reference pressure value and the measured pressure value, the reference pressure value indicative of the pressure on the distal segment at or near the pressure sensor when the distal segment is positioned in the biological fluid; and

compare the percentage difference to a plurality of predetermined contact assessment criteria and provide an indication result, the criteria and results comprising, for a percentage difference of at least approximately 75%, indicating substantially complete contact, for a percentage difference in the approximate range between 25% and 75%, indicating partial contact, and for a percentage difference less than approximately 20%, indicating no contact.

23. (original) The system of claim 20 wherein the pressure data comprises a sequence of pressure values indicative of the pressure on the distal segment over a period of time, and the processor is adapted to monitor the sequence of pressure values for variations indicative of contact between the distal segment at or near the pressure sensor and the tissue.

24. (original) The system of claim 23 wherein the processor is adapted to:

determine an average pressure value based on the sequence of pressure values;

calculate the standard deviation of the pressure values relative the average pressure;

calculate a deviation percentage;

compare the deviation percentage to a plurality of predetermined contact assessment criteria; and

provide an indication result, the criteria and results comprising, for a deviation percentage at least approximately 75%, indicating substantially complete contact, for a deviation percentage in the approximate range between 20% and 75%, indicating partial contact; and for a standard deviation percentage less than approximately 20%, indicating no contact.

25. (original) The system of claim 20 wherein:

the distal segment has a fluid-contacting area intended to contact the fluid and the system further comprises at least one flow sensor positioned within the fluid-contacting area and adapted to provide flow-rate data indicative of the flow rate of the fluid through the biological organ; and

the processor is adapted to receive the flow rate information, process the flow rate information to assess whether the fluid-flow rate is high or low and control the generator such that the generator provides energy of a first level to the electrode system during periods of high fluid-flow and energy of a second level, less than the first level, during periods of low fluid-flow.

26. (original) The system of claim 25 wherein the processor is adapted to control the generator to increase the energy level to the first energy level at the beginning of the high flow period and to decrease the energy level to the second energy level toward the end of the high flow period and before the beginning of the next low flow period.

27. (original) The system of claim 20 wherein:

the distal segment has a fluid-contacting area intended to contact the fluid and the system further comprises at least one flow sensor positioned within the fluid-contacting area and adapted to provide flow-rate data indicative of the flow rate of the fluid through the biological organ; and

the processor is adapted to control the generator such that the generator provides energy to the electrode system based on the flow-rate data.

28. (original) The system of claim 27 wherein a preset flow rate and a maximum energy level are programmed into the processor and the processor is adapted to:

compare the measured flow rate to the preset flow rate;

set the provided energy level to the maximum energy level when the measured flow rate is greater than or equal to the preset flow rate; and

determine the rate of reduction of the measured flow rate relative to the preset flow rate and set the provided energy level to a value less than the maximum energy level, the provided

level being a multiple of the maximum energy level, the multiple being set based on the determined reduction rate when the measured flow rate is less than the preset flow rate.

29. (original) The system of claim 20 further comprising:

a temperature sensor adapted to provide temperature signals to the processor, the signals indicative of the temperature at the electrode system;

wherein the processor is adapted to determine the temperature at the electrode system based on the temperature signals and to control the generator such that the level of energy applied to the electrode system maintains the temperature of the electrode system at or near a target temperature.

30. (previously presented) A system for assessing the adequacy of contact between an electrode and biological tissue within a biological organ having biological fluid therein, said system comprising:

a pressure sensor configured to provide a reference pressure indicative of the pressure at the electrode when the electrode is positioned in the biological fluid and configured to provide an assessment pressure indicative of the pressure at the electrode when the electrode is positioned proximal the biological tissue; and

a processor responsive to the reference and assessment pressure signals and configured to analyze the pressure signals and indicate the state of electrode/tissue contact, wherein the indication comprises a visual display of a degree of electrode/tissue contact.

31. (original) The system of claim 30 wherein the processor is adapted to:

determine the percentage difference between the reference pressure and the assessment pressure; and

compare the percentage difference to a plurality of predetermined contact assessment criteria and provide an indication result, the criteria and results comprising, for a percentage difference of at least approximately 75%, indicating substantially complete electrode/tissue contact, for a percentage difference in the approximate range between 20% and 75%, indicating

partial electrode/tissue contact, and for a percentage difference less than approximately 20%, indicating no electrode/tissue contact.

32. (original) The system of claim 30 wherein the pressure sensor is located on the electrode.

33. (original) The system of claim 30 wherein the pressure sensor is located adjacent the electrode.

34. (original) A method of assessing the adequacy of contact between an electrode and biological tissue within a biological organ having biological fluid therein, said method comprising:

positioning the electrode in the biological fluid;

obtaining a reference pressure value indicative of the pressure exerted on a region on or near the electrode;

moving the electrode to a position proximal the biological tissue;

obtaining an assessment pressure value by measuring the pressure exerted on the region on or near the electrode;

analyzing the assessment pressure and the reference pressure; and

indicating the state of electrode/tissue contact.

35. (original) The method of claim 34 wherein analyzing the assessment pressure and the reference pressure comprises calculating the percentage difference between the two and indicating the state of electrode/tissue contact comprises:

when the percentage difference is at least approximately 75%, indicating substantially complete electrode/tissue contact;

when the percentage difference is in the approximate range between 20% and 75%, indicating partial electrode/tissue contact; and

when the percentage difference is less than approximately 20%, indicating no electrode/tissue contact.

36. (original) The method of claim 34 wherein the reference pressure value is the average of a plurality of reference pressure values obtained during a given time period.

37. (original) The method of claim 34 wherein the assessment pressure value is the average value of a plurality of assessment pressure values obtained during a given time period.

38. (original) A system for assessing the adequacy of contact between an electrode and biological tissue within a biological organ having biological fluid therein, said system comprising:

an pressure sensor configured to provide assessment pressure values indicative of the pressure at the electrode; and

a processor adapted to:

sample a sequence of pressure values for a given time period; and

monitor the sequence of pressure values for variations indicative of electrode/tissue contact.

39. (original) The system of claim 38 wherein the processor is adapted to:

determine an average pressure value based on a plurality of the pressure values;

calculate the standard deviation of the pressure values relative the average pressure ;

calculate a deviation percentage;

compare the deviation percentage to a plurality of predetermined contact assessment criteria; and

provide an indication result, the criteria and results comprising, for a deviation percentage at least approximately 75%, indicating substantially complete electrode/tissue contact, for a deviation percentage in the approximate range between 25% and 75%, indicating partial

electrode/tissue contact; and for a standard deviation percentage less than approximately 20%, indicating no electrode/tissue contact.

40. (original) The system of claim 38 wherein the pressure sensor is located on the electrode.

41. (original) The system of claim 38 wherein the pressure sensor is located adjacent the electrode.

42. (original) A method of assessing the adequacy of contact between an electrode and biological tissue within a moving biological organ having biological fluid therein, said method comprising :

positioning the electrode proximal the biological tissue;

obtaining a sequence of pressure values by periodically measuring the pressure at the electrode during the time period; and

monitoring the sequence of pressure values for variations indicative of electrode/tissue contact.

43. (original) The method of claim 42 wherein monitoring the sequence of pressure values for variations indicative of electrode/tissue contact comprises:

obtaining an average pressure value based on a plurality of the pressure values;

calculating the standard deviation of the pressure values relative the average pressure;

calculating a deviation percentage;

when the deviation percentage is at least approximately 75%, indicating substantially complete electrode/tissue contact;

when the deviation percentage is in the approximate range between 20% and 75%, indicating partial electrode/tissue contact; and

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Serial No. 10/037,663
Client ID/Matter No. HRT-58192

when the deviation percentage is less than approximately 20%, indicating no electrode/tissue contact.

44. (currently amended) A method of assessing the adequacy of contact between a plurality of electrodes and biological tissue within a biological organ having biological fluid therein, said method comprising:

obtaining a reference pressure value for each electrode by:

positioning the plurality of electrodes in the biological fluid; and

measuring the pressure exerted at each electrode by the biological fluid;

moving the plurality of electrodes to a position proximal the biological tissue; and

for each electrode:

obtaining an assessment pressure value by measuring the pressure exerted at each electrode;

analyzing the assessment ~~impedance~~ pressure and the reference ~~impedance~~ pressure; and

indicating the state of electrode/tissue contact.

45. (previously presented) A system for applying energy to biological tissue within a biological organ having fluid flowing therethrough, said system comprising:

a generator for providing energy;

a catheter carrying an electrode system at its distal segment, the distal segment having a tissue-contacting area adapted to be positioned in the biological organ and intended to contact the biological tissue, the electrode system adapted to receive energy from the generator;

at least one pressure sensor associated with the distal segment, located within the tissue-contacting area and adapted to provide pressure data indicative of the pressure exerted on the distal segment at or near the pressure sensor; and

- 11 -

Serial No. 100037,663
Client ID/Matter No. HRT-58192

a processor responsive to the pressure data and configured to analyze the pressure data and provide an indication of contact between the distal segment at or near the pressure sensor and the tissue; wherein the processor is adapted to:

convert the pressure data to a measured pressure value;

determine the percentage difference between a reference pressure value and the measured pressure value, the reference pressure value indicative of the pressure on the distal segment at or near the pressure sensor when the distal segment is positioned in the biological fluid; and

compare the percentage difference to a plurality of predetermined contact assessment criteria and provide an indication result, the criteria and results comprising, for a percentage difference of at least approximately 75%, indicating substantially complete contact, for a percentage difference in the approximate range between 25% and 75%, indicating partial contact, and for a percentage difference less than approximately 20%, indicating no contact.

46. (previously presented) A system for applying energy to biological tissue within a biological organ having fluid flowing therethrough, said system comprising:

a generator for providing energy;

a catheter carrying an electrode system at its distal segment, the distal segment having a tissue-contacting area adapted to be positioned in the biological organ and intended to contact the biological tissue, the electrode system adapted to receive energy from the generator;

at least one pressure sensor associated with the distal segment, located within the tissue-contacting area and adapted to provide pressure data indicative of the pressure exerted on the distal segment at or near the pressure sensor; and

a processor responsive to the pressure data and configured to analyze the pressure data and provide an indication of contact between the distal segment at or near the pressure sensor and the tissue;

wherein the pressure data comprises a sequence of pressure values indicative of the pressure on the distal segment over a period of time and the processor is adapted to monitor the sequence of pressure values for variations indicative of contact between the distal segment at or near the pressure sensor and the tissue.

47. (previously presented) A system for applying energy to biological tissue within a biological organ having fluid flowing therethrough, said system comprising:

a generator for providing energy;

a catheter carrying an electrode system at its distal segment, the distal segment having a tissue-contacting area adapted to be positioned in the biological organ and intended to contact the biological tissue and a fluid-contacting area intended to contact the fluid, the electrode system adapted to receive energy from the generator;

at least one pressure sensor associated with the distal segment, located within the tissue-contacting area and adapted to provide pressure data indicative of the pressure exerted on the distal segment at or near the pressure sensor;

at least one flow sensor positioned within the fluid-contacting area and adapted to provide flow-rate data indicative of the flow rate of the fluid through the biological organ; and

a processor responsive to the pressure data and configured to:

analyze the pressure data and provide an indication of contact between the distal segment at or near the pressure sensor and the tissue; and

receive the flow rate information, process the flow rate information to assess whether the fluid-flow rate is high or low and control the generator such that the generator provides energy of a first level to the electrode system during periods of high fluid-flow and energy of a second level, less than the first level, during periods of low fluid-flow.

48. (previously presented) A system for applying energy to biological tissue within a biological organ having fluid flowing therethrough, said system comprising:

a generator for providing energy;

a catheter carrying an electrode system at its distal segment, the distal segment having a tissue-contacting area adapted to be positioned in the biological organ and intended to contact the biological tissue and a fluid-contacting area intended to contact the fluid, the electrode system adapted to receive energy from the generator;

at least one pressure sensor associated with the distal segment, located within the tissue-contacting area and adapted to provide pressure data indicative of the pressure exerted on the distal segment at or near the pressure sensor;

at least one flow sensor positioned within the fluid-contacting area and adapted to provide flow-rate data indicative of the flow rate of the fluid through the biological organ; and

a processor responsive to the pressure data and configured to:

analyze the pressure data and provide an indication of contact between the distal segment at or near the pressure sensor and the tissue; and

control the generator such that the generator provides energy to the electrode system based on the flow-rate data.

49. (previously presented) A system for assessing the adequacy of contact between an electrode and biological tissue within a biological organ having biological fluid therein, said system comprising:

a pressure sensor located on the electrode and configured to provide a reference pressure indicative of the pressure at the electrode when the electrode is positioned in the biological fluid and configured to provide an assessment pressure indicative of the pressure at the electrode when the electrode is positioned proximal the biological tissue; and

a processor responsive to the reference and assessment pressure signals and configured to analyze the pressure signals and indicate the state of electrode/tissue contact.

50. (previously presented) A system for assessing the adequacy of contact between an electrode and biological tissue within a biological organ having biological fluid therein, said system comprising:

a pressure sensor located adjacent the electrode and configured to provide a reference pressure indicative of the pressure at the electrode when the electrode is positioned in the biological fluid and configured to provide an assessment pressure indicative of the pressure at the electrode when the electrode is positioned proximal the biological tissue; and

a processor responsive to the reference and assessment pressure signals and configured to analyze the pressure signals and indicate the state of electrode/tissue contact.